JUN 1 5 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The Implex Hedrocel® Modular Elliptical Acetabular Cup

Submitter Name: Implex Corp.

Submitter Address: 80 Commerce Drive
Allendale, New Jersey 07401-1600

Contact Person: John Schalago or Robert Poggie

Phone Number: (201) 818-1800

Fax Number: (201) 995-9722

Date Prepared: March 27, 2000

Device Trade Name: The Implex Hedrocel® Modular Elliptical Acetabular Cup

Device Common Name: Acetabular Cup

Classification Number and Name: 21 CFR § 888.3358

Substantial Equivalence: **The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.**

Device Description: The Implex Hedrocel® Modular Elliptical Acetabular Cup System is a modular acetabular cup consisting of an elliptical porous tantalum with dome screw holes, a metal locking ring, and an ultra-high molecular weight polyethylene (UHMWPE, ASTM F-648) bearing insert. The Implex Hedrocel® Modular Elliptical Acetabular Cup is available in OD sizes from 40 mm to 70 mm, in 2 mm increments. The ultra-high molecular weight polyethylene bearing inserts are available with four ID size options (22 mm, 26 mm, 28 mm, and 32 mm) and in 0°, 10°, and 20° face angles. The outer rim has scallops that allow the surgeon to dial in the insert face angle relative to the seated shell.

510(k) Summary (Continued)

Device Description (cont'd):

The Implex Hedrocel® Modular Elliptical Acetabular Cup is intended for use with 6.5 mm and 5.0 mm diameter cancellous bone screws in 20 to 65 mm lengths, in 5 mm increments. A titanium alloy dome hole plug is available for sealing the central dome hole.

Indications for Use:

The Implex Hedrocel® Modular Elliptical Acetabular Cup is intended for use where severe degeneration, trauma, or other pathology of the hip joint indicates cemented, cementless or hybrid total hip arthroplasty.

Device Technological Characteristics and Comparison to Predicate Device:

The subject device and the predicate devices are manufactured from similar materials, have similar insert locking mechanisms, have similar or the same indications for use, and utilize similar surgical techniques and instrumentation.

Performance Data:

The Hedrocel/Titanium alloy interface was tested per applicable FDA Guidance Documents and ASTM Standards (or draft standards) and the results demonstrated that the interface will maintain its integrity under physiological loads.

Conclusion:

The Implex Hedrocel® Modular Elliptical Acetabular Cup is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2000

Mr. John A. Schalago
Manager, Regulatory Affairs
Implex Corporation
80 commerce Drive
Allendale, New Jersey 07401-1600

Re: K001039
Trade Name: Implex Hedrocel Modular Elliptical Acetabular Cup
Regulatory Class: II
Product Code: LPH, JDI
Dated: March 27, 2000
Received: March 31, 2000

Dear Mr. Schalago:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001039

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Diane R. Vochmer

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001039

Prescription Use (Per 21 CFR 801.109) Yes OR... Over-The-Counter Use No

(Optional Format 1-2-96)